Remarks

Rejections - 35 U.S.C. § 102(e)

Claims 1-2, 4-11, 14-20, 41-61 and 63 were rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Reiley (US Patent Publication Number 2002/0123806; cited by Applicant). It is respectfully requested that the Examiner reconsider the rejection based on Reiley.

The present invention relates to providing an artificial articulating surface on a facet (inferior and/or superior). Independent claims 1, 14, 20 and 53 all recite implants "***configured for placement on***" an ***articular facet***. And independent claims 41, 47 and 63 all recite "***providing an artificial articulating surface on***" an ***articular facet***. Reiley does not disclose any implant configured for placement on an articular facet, nor does Reiley disclose any means for providing an artificial articulating surface on an articular facet. Instead, Reiley discloses a facet replacement system. None of the structures disclosed in Reiley are capable of being placed on an articular facet. In fact, Reiley teaches away from the claimed invention because Reiley requires the resection of the articular facet being treated.

Anatomy of the Lumbar Spine

As explained in the background section and illustrated in Figure 3 of the present application, the laminae of the spine have various structures, including the superior facet, inferior facet, superior articulating surface and inferior articulating surface. Notably, structures 30 and 32 of Figure 3 are the "articular facets" referenced in the claims of the present invention:

> Turning now to Figures 2 and 3, normal human lumbar vertebrae 12 are illustrated. It will be understood by those skilled in the art that while the lumbar vertebrae 12 vary somewhat according to location, they share many features common to most vertebrae 12. Each vertebra 12 includes a vertebral body 14. Two short bones, the pedicles 16, extend backward from each side of the vertebral body 14 to form a vertebral arch 18. At the posterior end of each pedicle 16, the vertebral arch 18 flares out into broad plates of bone known as the laminae 20. The laminae 20 fuse with each

other to form a spinous process 22. The spinuous process 22 provides muscle and ligament attachment.

The transition from the pedicles 16 to the laminae 20 is interrupted by a series of processes. Two transverse processes 24 thrust out laterally on each side from the junction of the pedicle 16 and the lamina 20. The transverse processes 24 serve as guides for the attachment of muscles to the vertebrae 12. Four articular processes, two superior 26 and two inferior 28, also rise from the junctions of the pedicles 16 and the laminae 20. The superior articular processes 26 are oval plates of bone rising upward on each side from the union of the pedicle 16 with the lamina 20. The inferior processes 28 are oval plates of bone jutting downward on each side. The superior and inferior articular processes 26 and 28, respectively, each have a natural bony structure known as a facet. The superior articular facet 30 faces upward, while the inferior articular facet 32 faces downward. The superior articular facet 30 and the inferior articular facet 32 have articulating surfaces 38 and 40, respectively.

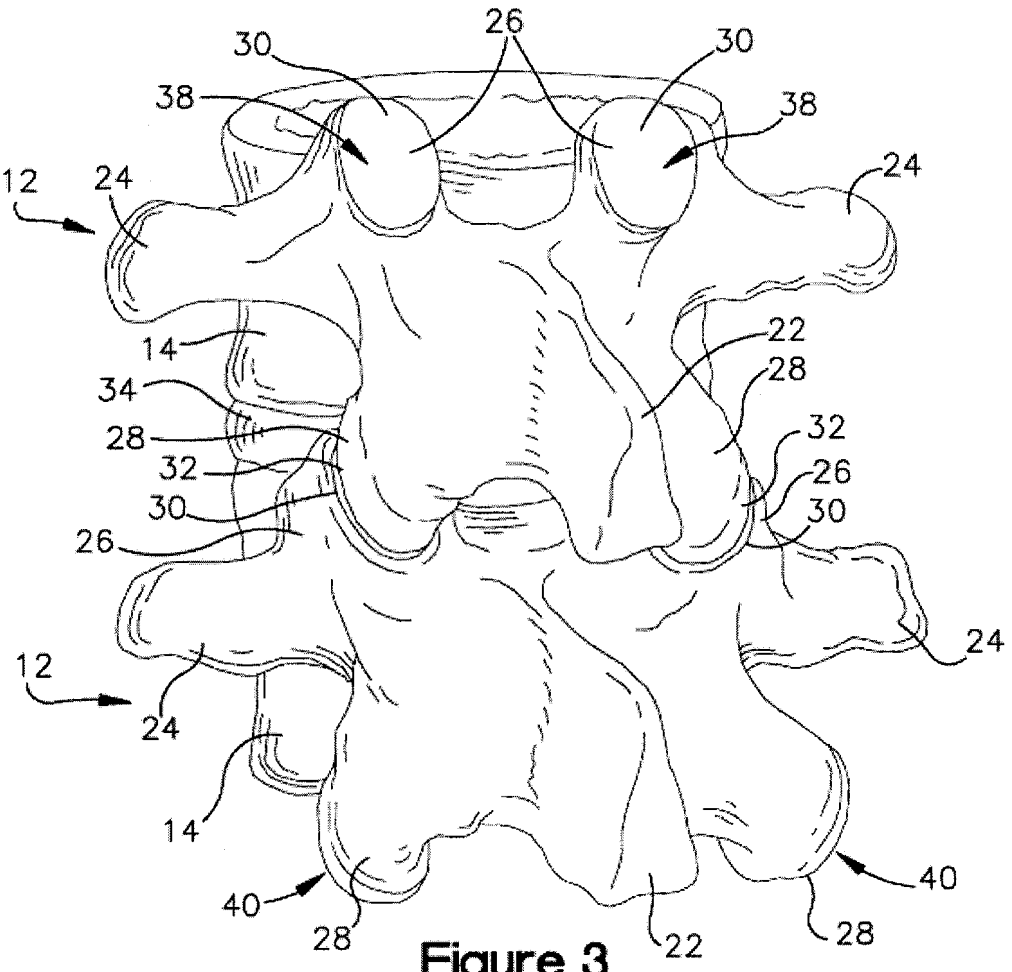

Figure 3

Bogduk, Nikolai, Clinical Anatomy of the Lumbar Spine and Sacrum, 4th ed. Elsevier, Churchill, Livingstone; 2005 (See Ex. A) is also instructive:

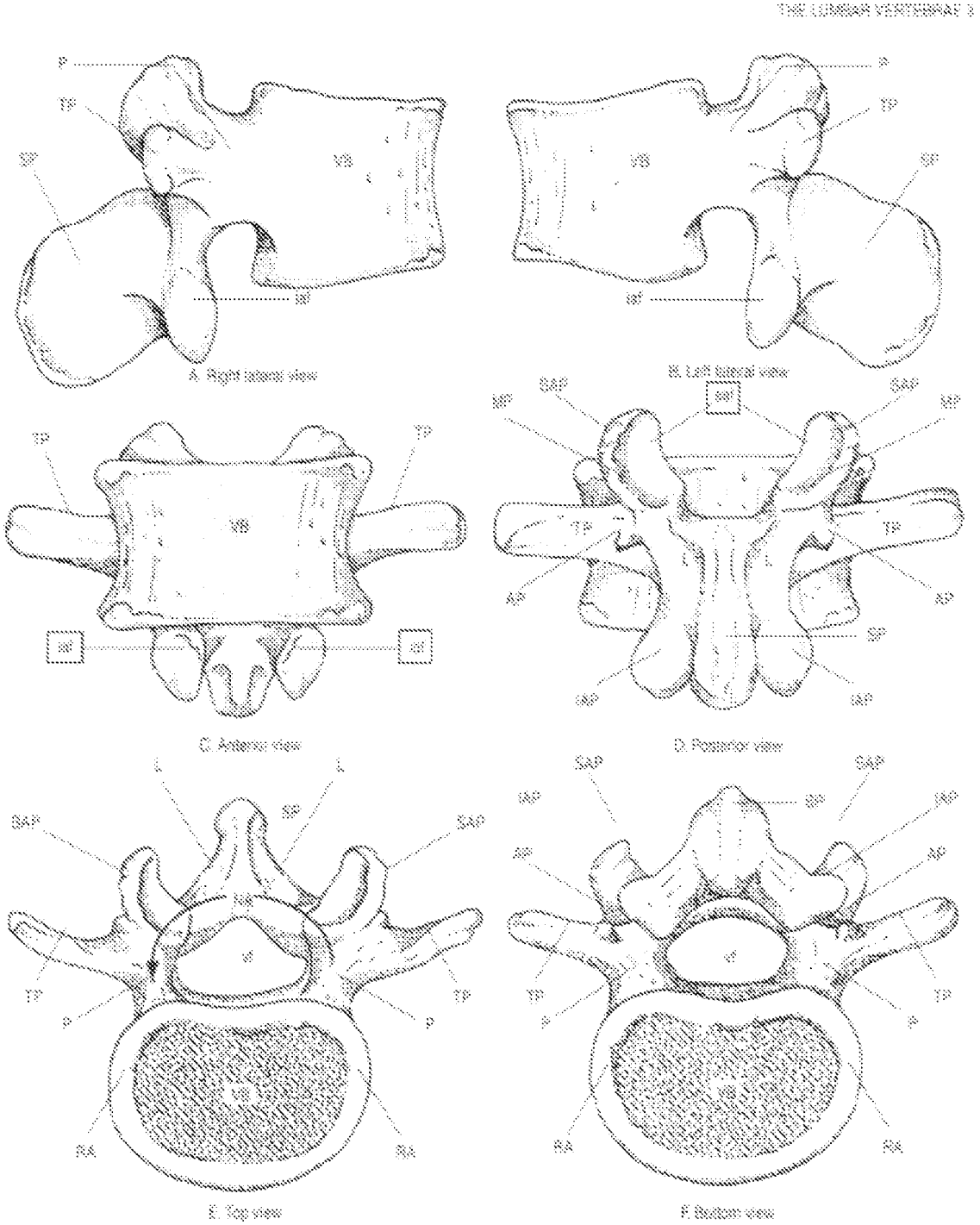

Figure 1.2 The parts of a typical lumbar vertebra: AP, accessory process; IAF, inferior articular facet; IAP, inferior articular process; L, lamina; MP, mammillary process; NA, neural arch; P, pedicle; RA, ring apophysis; SAF, superior articular facet; SAP, superior articular process; SP, spinous process; TP, transverse process; VB, vertebral body; vf, vertebral foramen.

Reiley

Unlike the present invention, Reiley is directed to an apparatus that ***replaces*** the articular facet, not an apparatus configured for ***placement on*** an articular facet. Figures 1 and 2 of Reiley are depictions of vertebrae and Figures 3-5 and 7-9 illustrate the devices of Reiley as they are used to treat vertebrae. It is clear in each of Figures 3-5 and 7-9 that the entire facet (superior or inferior) is resected and the apparatus of Reiley replaces the removed facet.

To remove any doubt regarding the nature of the Reiley device, Reiley explains throughout the specification that the prosthetic system is for replacing facet structures. Reiley refers to replacing the caudal portion or cephalad portion of the facet joint. As Reiley explains, this means either the entire superior half of the joint or the entire inferior half of the joint:

> "..... a given natural facet joint has a superior half and an inferior half..... the **superior half** of the joint is formed by the vertebral level below the joint (Which can thus be called the **caudal portion** of the facet joint, i.e. because it is near the feet). The **inferior half** of the joint is formed by the vertebral level above the joint (Which can thus be called the **cephalad portion** of the facet joint, i.e. because it is near the head)." (¶13, emphasis added).

Indeed, from Reiley's definition of the "caudal portion" and "cephalad portion" of the facet joint, it is clear that Reiley discloses only a system for replacing either the entire superior half of the joint or the entire inferior half of the joint:

> "There is a need in the field for prostheses and prosthetic systems to **replace** injured and/ or diseased facet joints....." (¶1, emphasis added).

> "One aspect of the invention provides for a facet joint prosthesis to **replace**, on a **vertebral body**, a **caudal portion** of a **natural facet joint** (e.g. a superior articular surface **and** supporting bone structure on the vertebral body). ... the caudal prosthesis includes an artificial facet joint structure adapted to **replace** a caudal portion of the natural facet joint after its **removal** from the vertebral body. The **removal** of a caudal portion of the natural facet joint and its **total replacement** by the artificial facet joint structure of the caudal prosthesis, frees the orientation of the prosthesis from anatomic constraints imposed by a preexisting articular configuration of the **caudal portion of the natural facet joint**". (¶15, emphasis added).

> "This aspect of the invention also provides a method of **replacing** on a **vertebral body**, a **caudal portion** of a **natural facet joint.** The method **removes** a caudal portion of the natural facet joint from the **vertebral body**,

and, **in its place**, fixes a component to the **vertebral body** that includes an artificial facet joint structure adapted to **replace** the **removed** caudal portion of the **natural facet joint**. Desirably, the artificial facet joint structure includes an artificial articular configuration **unlike** the preexisting articular configuration of the **removed caudal portion of the natural facet joint**." (¶16, emphasis added).

Another aspect of the invention provides a facet joint prosthesis to **replace**, on a **vertebral body,** a **cephalad portion** of a **natural facet joint** e.g. an inferior articular surface and supporting bone structure on the vertebral body). The cephalad prosthesis comprises a component sized to be fixed to the vertebral body, *e.g. on or near a pedicle , or on or near a lamina .... or combinations thereof*. The cephalad prosthesis includes an artificial facet joint structure adapted to replace a cephalad portion of the natural facet joint after its removal from the vertebral body. ... The **removal** of a cephalad portion of the natural facet joint and its **total replacement** by the artificial facet joint structure of the cephalad prosthesis, frees the orientation of the prosthesis from anatomic constraints imposed by a preexisting articular configuration of the **cephalad portion of the natural facet joint**". (¶17, emphasis added).

"This aspect of the invention also provides a method of **replacing** on a **vertebral body**, a **cephalad portion** of a **natural facet joint.** The method **removes** a cephalad portion of the natural facet joint from the **vertebral body**, and, **in its place**, fixes a component to the **vertebral body** that includes an artificial facet joint structure adapted to **replace** the **removed** cephalad portion of the **natural facet joint**. Desirably, the artificial facet joint structure includes an artificial articular configuration **unlike** the preexisting articular configuration of the **removed cephalad portion of the natural facet joint**." (¶18, emphasis added).

Another aspect of the invention provides a prosthesis assembly and related method for **replacing** a natural facet joint between adjoining first vertebral body and a second vertebral bodies. ... the first component includes a first artificial facet joint structure adapted to **replace** a cephalad portion of the natural facet joint **on the first vertebral body** after **removal** of the **cephalad portion of the natural facet joint** from the first vertebral body. ... the second component includes a second artificial facet joint structure adapted to **replace** the caudal portion of the **natural facet joint** of the second vertebral body **after removal** of the caudad portion of the **natural facet** from the second vertebral body". (¶19, emphasis added).

"Fig. 3 shows a caudal facet **joint replacement prosthesis** 26 ... it creates an artificial facet joint structure 28 for the superior half of a facet **joint replacement**. The caudal prosthesis 26 allows for the **removal and replacement** of injured, diseased and/or deteriorating natural superior

articular surfaces **and** supporting boney structure on the vertebral body **below the facet joint**..." (¶39, emphasis added).

"... in the preferred embodiment, the prosthesis 26 is used to **replace** the caudal portion of one or more facet joints." (¶60, emphasis added).

"A surgical procedure **removes and replaces** the caudal portion of a facet joint with the caudal prosthesis 26...." (¶64, emphasis added).

"Fig 9 shows a cephalad facet joint **replacement** prosthesis 48 ... the cephalad prosthesis 48 allows for the **removal and replacement** of injured, diseased, and/or deteriorating natural inferior articular surfaces **and** supporting boney structure on the vertebral body above the facet joint..." (¶70, emphasis added).

"The cephalad prosthesis 48 shown in fig 9 desirably spans the lamina 16 from the left side of the vertebral body 10 to the right side of the vertebral body10. ... The cephalad prosthesis 48 allows for **replacement** of diseased and deteriorating inferior portions of the vertebra and **partial replacement of lamina**... the cephalad prosthesis 48 creates **artificial** facet joint structure elements 50 for the **inferior half of facet joints** in the spine..." (¶73, emphasis added).

Reiley also makes clear that the disclosed apparatus is configured for attachment to the lamina and pedicle—not the inferior or superior facet:

"The cephalad prosthesis 48 as described above is placed **over** the spinous process 18 **over** the lamina 16. The cephalad prosthesis 48 is **attached** as above described to the **lamina** 16 **and** to **each pedicle**. The cephalad prosthesis 48 may also be further attached to the **spinous process** 18 with a transspinous process screw 66 to provide additional stability,..." (¶98, emphasis added).

Finally, Reiley leaves no doubt that the superior or inferior facet ***must be removed*** in order to install the apparatus:

"...**because the caudal portion of the natural facet joint has been removed**, the artificial facet joint structure of the caudal prosthesis 26 can be installed in a desired position...." (¶66, emphasis added).

"Because the cephalad portion of the **natural facet joint** is **removed**..." (¶74, emphasis added).

"As fig 9 shows, the caudal prosthesis 26, e.g. as described above, may also be installed with the cephalad prosthesis 48, to **replace** both the caudal and cephalad portions of the natural facet joint, **after both caudal and cephalad portions of the natural facet joint are surgically removed**. **Together**, the

caudal and cephalad prostheses 26 and 48 form **a total facet replacement system** 52." (¶75, emphasis added).

"Because the system 52 entails **removal** of **both** the caudal and cephalad **portions** of the **natural facet joints**,..." (¶76, emphasis added).

Accordingly, it is respectfully submitted that Reiley neither discloses nor suggests an apparatus "***configured for placement on***" an ***articular facet*** as set forth in any independent claims 1, 14, 20 or 53. It is also respectfully submitted that Reiley neither discloses nor suggests "***providing an artificial articulating surface on***" an ***articular facet*** as set forth in any of independent claims 41, 47 or 63. Accordingly, it is submitted that claims 1-2, 4-11, 14-20, 41-61 and 63 are in condition for allowance.

Rejections - 35 U.S.C. § 103

Claims 3, 12 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Reiley. For the reasons discussed above, Reiley does not meet the limitations of the independent claims.

Accordingly, it is respectfully submitted that claims 3, 12 and 13 are in condition for allowance.

Conclusion

It is submitted that this application is in condition for allowance and an early action to that effect is earnestly solicited. In the event that the Examiner has any questions regarding the arguments presented herein, the Examiner is invited to contact the Applicant's representative.

Respectfully submitted,

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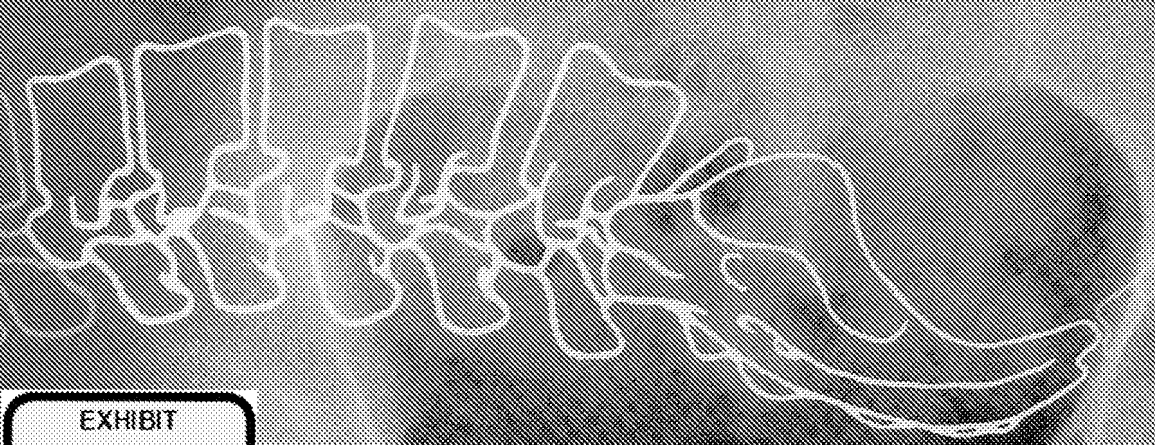
Clinical Anatomy of the Lumbar Spine and Sacrum

Nikolai Bogduk

Foreword by Dr Steve Eadie



Clinical Anatomy of the Lumbar Spine and Sacrum

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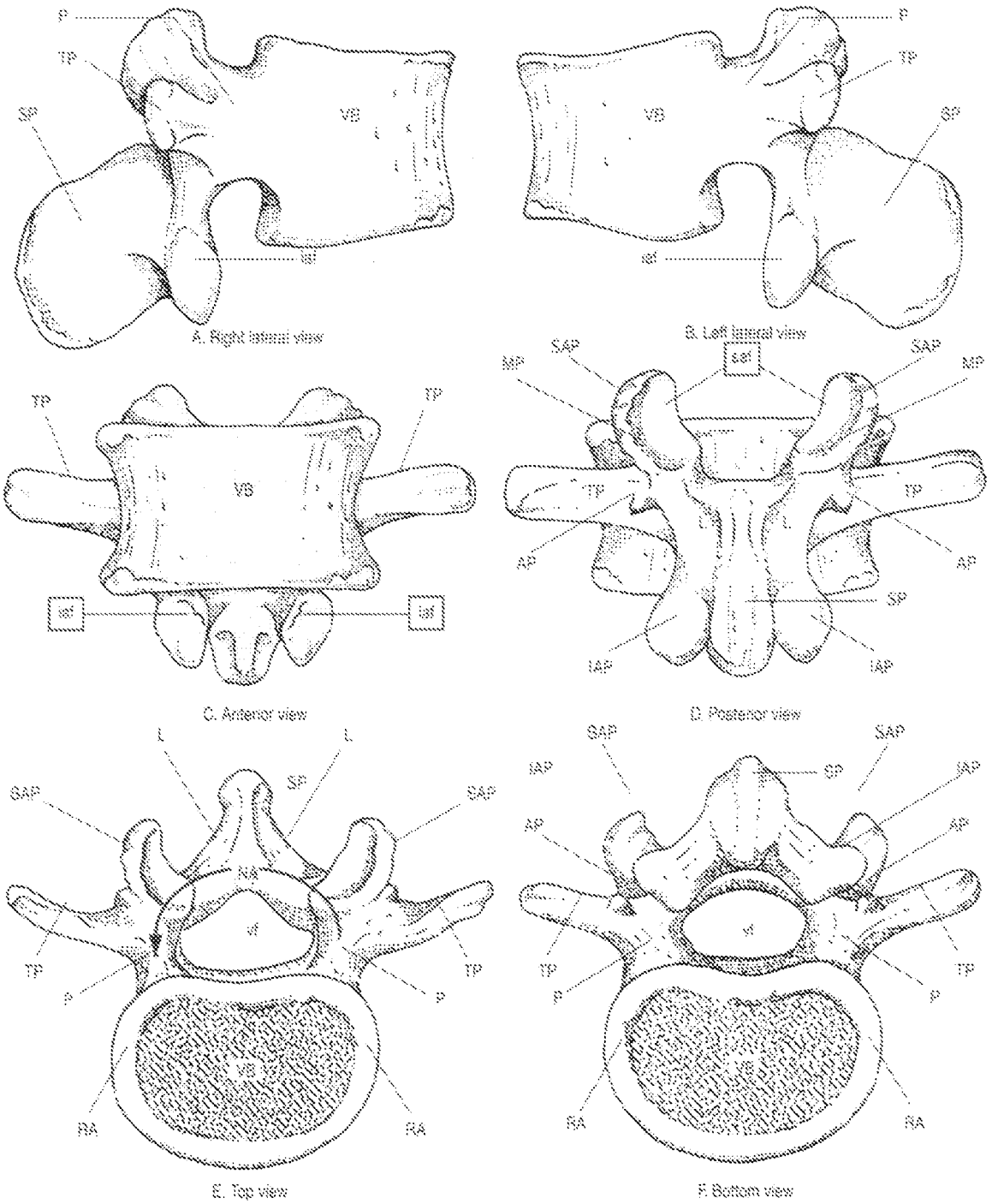

Figure 1.2 The parts of a typical lumbar vertebra: AP, accessory process; isf, inferior articular facet; IAP, inferior articular process; L, lamina; MP, mamillary process; NA, neural arch; P, pedicle; RA, ring apophysis; ssf, superior articular facet; SAP, superior articular process; SP, spinous process; TP, transverse process; VB, vertebral body; vf, vertebral foramen.